

UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION

INTERNATIONAL DAIRY FOODS  
ASSOCIATION

and

ORGANIC TRADE ASSOCIATION

Plaintiffs,

v.

ROBERT J. BOGGS  
(solely in his official capacity as Ohio Director  
of Agriculture)

Defendant.

CASE NO.: 2:08-CV-628, 629

Judge: Graham

ORAL ARGUMENT REQUESTED

**REPLY IN SUPPORT OF PLAINTIFF INTERNATIONAL DAIRY FOODS  
ASSOCIATIONS' MOTION FOR SUMMARY JUDGMENT**

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## INTRODUCTION

The Ohio Department of Agriculture's ("ODA") opposition brief<sup>1</sup> and subsequent depositions of Mr. Boggs and Mr. Jones serve to highlight, not undercut, the Constitutional infirmities in the Ohio Rule challenged here. ODA acknowledges that this is a legal case and not one that is fact dependent, conceding the factual posture of the case as presented in the Plaintiffs' opening briefs. As discussed below, ODA cannot carry any of his burdens under First Amendment analysis given this admission. The shifting sands of ODA's argument cannot forestall judgment against ODA for having banned non-misleading, accurate speech and further regulating speech that is not even potentially misleading.

As with so many other unconstitutional restrictions and limitations on commercial speech, ODA recites by rote that the existing labels are misleading, skipping the first test of *Central Hudson* as if it does not exist. Similarly the next two prongs of *Central Hudson* – state substantial interest and whether the regulation advances that interest – are glossed over. As repeatedly stated by the U.S. Supreme Court, the harm must be real, not based upon speculation and the regulation must actually alleviate the harm. However, ODA's position is rife with speculation – e.g., that consumers are misled, that claims cannot be verified, that asterisks are confusing and that the Ohio Rule actually addresses alleged problems. ODA misses the point of Consumer interest in non-use of rbST and simply assumes that consumers are or, to the extent relevant, may be misled by these labels. Nothing in the Record before this Court supports those surmises and assumptions. And those surmises and assumptions are legally insufficient.

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<sup>1</sup> Defendant identifies its brief as a Motion for Summary Judgment as well as a Memorandum in Opposition. This Reply filed by IDFA shall also serve as IDFA's opposition to ODA's Motion for Summary Judgment as ODA's Motion, which is identical to their Opposition, is mutually exclusive of IDFA's Motion and Memorandum in Support of Summary Judgment against the Ohio Rule.

Since it cannot meet the prongs of *Central Hudson*, ODA concocts an unsupported proposition, that *Central Hudson* and its intermediate, but high, standard of review do not apply. This position is flatly contradicted by the U.S. Supreme Court's decision in *Ibanez*, decided nine years after *Zauderer* (the dicta of which is relied upon by ODA). With a factual posture indistinguishable from this case (Florida in *Ibanez* proposed to ban some speech and regulate through forced explanatory language) ODA's position is demolished.

Finally, ODA's thin analysis of the dormant commerce clause claim fails to acknowledge even that the Ohio Rule has clear and intended extraterritorial effects. Further, the Ohio Rule discriminates against interstate commerce by imposing greater costs on national labels than on local labels and by taking away the competitive advantages enjoyed by non-Ohio dairy farmers and processors who have established a market for milk produced from cows not treated with rbST.

The Ohio Rule cannot stand.

## **ARGUMENT**

### **I. ODA has not satisfied its burden of justifying the Rule's restrictions on processor commercial speech rights**

#### **A. ODA Has Not Satisfied Its Burden Of Justifying A Prophylactic Ban On Speech**

Although ODA discusses three different types of banned speech in the same section of its brief, a careful review reveals that the sole justification in support of its ban on phrases such as "No rbST" or "rbST Free," which are the banned phrases with which this lawsuit is concerned, is that it cannot be verified that milk has "No rbST." This somehow, for reasons not explained, creates the unacceptable risk of misleading consumers regarding the content of the dairy products they consume. (Def's Mem. Opp'n Summ. J. ("Mem. Opp'n") 6.) Further, ODA



claims that this renders phrases such as “No rbST” misleading and this somehow justifies ODA’s prophylactic ban on the use of these terms as articulated in section (C) of the Rule.

**1. ODA’s purported justification for the ban is incorrect**

Importantly, however, ODA’s effort at concocting a syllogism fails because its major premise - the assertion that the statement cannot be verified - is incorrect. As acknowledged by ODA under examination during depositions on September 3, 2008, it is a truism that if rbST is not injected into cows, then the milk from those cows will not contain rbST. (Deposition of Robert J. Boggs (“Boggs Dep.”) 84:8-85:4, Sept. 3, 2008.)<sup>2</sup> Since ODA has acknowledged that a farmer and its processor partner can verify that no rbST was used in production of milk, by its very own verification requirements articulated in section (B)(1) of the Rule, Ohio Admin. Code 901:11-8-01, ODA cannot now turn around and legitimately assert that the statement “No rbST” cannot be verified. Since the assertions made by such phrases can in fact be verified, notwithstanding the unavailability of a test for commercial use, it does not follow then that the inability to verify creates the unacceptable risk of misleading consumers regarding the content of the dairy products they consume.

Of greater significance, however, is the fact that IDFA’s members are not seeking to use phrases such as “No rbST” in isolation. As stated in the opening brief, this lawsuit is brought to ensure that IDFA’s non-organic members may label their dairy products in accordance with the FDA guidance, just as they have for 14 years. (IDFA’s Mem. Supp. Summ. J. (“Mem. Supp.”) 1.) As a result, ODA’s tortured explanation of the so-called problem with such stand alone phrases as “No rbST” misses the point altogether. It is a red herring. The FDA guidance, as explained more fully in IDFA’s opening brief created a safe harbor that allows for phrases such

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<sup>2</sup> Relevant excerpts are attached hereto in the Appendix in Support of Summary Judgment Reply 0623-0652 (hereinafter “S.J.R. App. III”).

as “No Artificial Growth Hormones” when such phrases are placed in a production context with other language such as a further statement that “Our Farmers Pledge Not To Use rbST” or the so-called disclaimer that reads “No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows.” Indeed, many of the labels in use at the time the Rule was adopted included all three components.<sup>3</sup> However, ODA has banned the use of the particular words such as “No Artificial Growth Hormones” and “No rbST” even when placed in context as described above. Ohio Admin. Code 901:11-8-01; (*see also* Deposition of Lewis R. Jones (“Jones Dep.”) 80:9-15; 81:14-20, Sept. 3, 2008.)<sup>4</sup> Since neither the rulemaking record nor ODA in its Opposition reveal evidence that labels that conform to the FDA safe harbor are in fact misleading, ODA has not (and cannot) satisfy its burden of establishing that the use of “No rbST” in the context of the FDA safe harbor is in fact misleading. (*See also* Mem. Supp. 23-25.)

## **2. ODA’s argument is also legally flawed**

ODA’s Opposition fails to justify the Rule’s ban on speech. Even as ODA properly credits *Central Hudson* with a clear articulation of the analytical framework for addressing the validity of speech restrictions, its analysis is fatally flawed because it stops with *Central Hudson* to the exclusion of more than three decades of Supreme Court precedent refining First Amendment analysis as it relates to prophylactic bans on speech like the one ODA has adopted here. Indeed, it is correct that misleading speech, false speech or speech related to unlawful activity, is beyond the protection of the First Amendment.<sup>5</sup> *In re R.M.J.*, 455 U.S. 191, 200 (1982) (“False, deceptive, or misleading advertising remains subject to restraint....”) The states

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<sup>3</sup> Amicus dairy farmers essentially argue, without citation to the Record, that all these labels are false and disparaging. The opening paragraph of that Amicus Brief is especially telling if only because it proves one of IDFA’s central points, that the only persons who are upset about existing labels are not consumers, but the farmers who are being asked to forego a technology not yet accepted by consumers.

<sup>4</sup> Relevant excerpts are attached hereto at S.J.R. App. III 0653-0689.

<sup>5</sup> ODA does not argue that phrases such as “No Artificial Growth Hormones” are false or related to unlawful activity.

or Federal government certainly may prohibit speech that is actually misleading or that falls into the other two categories, but the Supreme Court precedent dealing with prophylactic bans reveals that the Court has only sanctioned prophylactic bans in two limited circumstances: (1) A prophylactic ban might be permitted if there is history of actual deception and abuse worked upon the public (*In re R.M.J.* 455 U.S. at 202 (citing *Friedman v. Rogers*, 440 U.S. 1 (1979))); and (2) A prophylactic ban might be permitted if the speech at issue is inherently misleading. *Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626, 641 & 644 (1985) (“Indeed, in *In re R.M.J.* we went so far as to state that ‘the States may not place an absolute prohibition on certain types of potentially misleading information ... if the information also may be presented in a way that is not deceptive.’”); *see also In re R.M.J.*, 455 U.S. at 203 (“when the particular content or method of the advertising suggests that it is *inherently misleading* or when experience has proved that in fact such advertising is *subject to abuse*, the States may impose appropriate restrictions.” (emphasis added)); *Edenfield v. Fane*, 507 U.S. 761, 774 (1993) (citing *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447 (1978) for the proposition that prophylactic bans are only justifiable where there is an inherent problem with the speech or misconduct, which in *Ohralik* was the potential for overreaching by in-person solicitation by lawyers rather than a concern for misleading).

Moreover, these categories are consistent with the overriding principle underlying First Amendment jurisprudence that less speech, not more, should be restricted. *Edenfield*, 507 U.S. at 766; *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557, 563 (1980). In service of this principle, the Court has noted that it is for this reason that prophylactic bans are disfavored, stating: “Our recent decisions involving commercial speech have been grounded in the faith that the free flow of commercial information is valuable enough

to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful.” *Zauderer*, 471 U.S. at 646. For instance in *Zauderer*, after concluding that a prophylactic ban was not justified because the speech at issue was not inherently misleading, the Court rejected the State’s argument that the prophylactic ban was justified because it would be too difficult to distinguish between acceptable and unacceptable advertising. *Id.* at 647. Thus, these cases demonstrate that although misleading speech may be prohibited by regulators as articulated in *Central Hudson*, free speech principles strictly circumscribe the circumstances under which prophylactic bans are permitted. *See also id.* at 646 & 648 (demonstrating the Court’s concern with permitting prophylactic bans in the absence of evidence that the harm will recur enough to justify such a ban over regulatory oversight).

### **3. ODA has not shown that the asserted risk warrants a prophylactic ban**

ODA’s ban does not fit into the categories of circumstances that have historically justified a prophylactic ban. At best, ODA by adoption of the ban has improperly abdicated its responsibility to sort through the various labeling claims being used in Ohio under existing authority, and at worst, ODA has adopted a ban that rather than helping consumers appears to help Monsanto and dairy farmers as explained in IDFA’s opening brief. (Mem. Supp. 4-5.) Notably, other than conclusory assertions to the contrary, ODA offers no evidence to dispute these facts and more importantly, fails to carry its burden of establishing that there is a history of deception or that the speech at issue is inherently misleading.

#### **a. There is no history of deception**

ODA does not and cannot argue that there has been a history of deception and abuse worked upon the public. In *Friedman*, one of the rare instances in which a prophylactic ban was

upheld, the Supreme Court concluded that because of a demonstrated history of abuse and deception associated with Optometrists using trade names, a prophylactic ban on the use of trade names was justified. *Friedman*, 440 U.S. at 13. In that case, however, the evidence of historical deception was robust. For instance the legislature was aware when it enacted the ban that trade names had been used to: mislead the public into believing there was competition among practices when there was not; and to mislead the public into believing that particular staff were working in a particular location, among other things. *Id.* at 14 (citing *Texas State Bd. of Examiners in Optometry v. Carp*, 412 S.W.2d 307 (Tex. 1967)).

ODA has offered no evidence of a history of deception and abuse worked on the public. There is no evidence in the rulemaking record and there is no such assertion in ODA's Opposition that labels using the banned speech consistent with the FDA guidance have actually, let alone systematically, been a problem. Indeed, both Chief Jones and Director Boggs admitted that rather than a history of deception giving rise to the Rule, the rulemaking process resulted from the debate that began after the neighboring state of Pennsylvania adopted guidance with respect to rbST labeling. (Jones Dep. 7:18-8:3; 41:23-42:13; Boggs Dep. 8:6-16.) In fact, Chief Jones admitted that there was no history of consumer complaints or enforcement actions before October 2007 and went so far as to admit that the FDA Guidance was working just fine. (Jones Dep. 22:16-18; 22:24-23:4.)

**b. The banned speech is not inherently misleading**

Nor can ODA justify the ban on the basis that the banned phrases are inherently misleading.

**(i) Labels that follow the FDA guidance provide sufficient context such that they are not inherently misleading**

Governmental agencies like ODA are not prevented from prohibiting speech that is actually misleading, but where that speech can be placed in a context that is not misleading, the government is permitted to police that speech rather than adopt a prophylactic ban against that speech. *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, Bd. of Accountancy*, 512 U.S. 136, 143 (1994) (citing *Zauderer*, 471 U.S. at 648-49 (“broad prophylactic rules may not so lightly be justified if the protections afforded commercial speech are to retain their force.”)). Thus, the Supreme Court has now long held that: “[T]he States may not place an absolute prohibition on certain types of potentially misleading information...if the information also may be presented in a way that is not deceptive.” *Zauderer*, 471 U.S. at 644 (quoting *In re R.M.J.*, 455 U.S. at 203).

Contrary to Supreme Court precedent, section C of the Rule has banned phrases such as “No rbST” even when it is placed in a context that the FDA determined was sufficient to avoid misleading the public.<sup>6</sup> Chief Jones confirmed, under examination, that Hood Company’s national Lactaid label (P.I. App. 0432)<sup>7</sup>, which conforms to the FDA guidance in that it contains the phrase “No Artificial Growth Hormones” makes clear that their farmers are making the pledge and then contains the FDA disclaimer on the same panel would not be acceptable because it contains the words “No Artificial Growth Hormones.” (Jones Dep. 79:9-80:17.) Even when asked if the Department’s position would change if the label made it clearer that the “No Artificial Growth Hormones” claim was made by their dairy farmers by adding the phrase below the claim “Our Farmers Pledge Not To Use Artificial Growth Hormones,” the Chief indicated “probably not,” instead suggesting the Department would allow the label if the phrase “No Artificial Hormones” were removed. (Jones Dep. 80:12.) This testimony merely serves to

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<sup>6</sup> The U.S. Department of Health and Human Services (“HHS”) conducted a study and concluded that “virtually all consumers” understand the use of asterisks to link statements. SSUF ¶46. The Director simply disagrees with HHS because of his own subjective observations at supermarkets. (Boggs Dep. 87:14-88:2.)

<sup>7</sup> Appendix in support of Preliminary Injunction (“P.I. App.”).

confirm IDFA's understanding of the Rule that there is no circumstance under which ODA will permit phrases such as "No rbST" or "No Artificial Growth Hormones" even when put into context. In this case, the Lactaid label itself, and the Lactaid label as modified for purposes of deposition examination, both remove through context the *possible* implication of a composition claim. Nevertheless, ODA's Rule bans the speech. This kind of prophylactic prohibition, that ignores the Supreme Court's jurisprudence that speech should be permitted if context renders it non-misleading, flatly violates the First Amendment.

(ii) **Labels that contain phrases such as "No rbST" are objective and verifiable speech and are not inherently misleading**

Further, since the statement "No rbST" can be verified based upon non-use certifications by farmers and processors, it does not follow that such statements are inherently misleading. See *Peel v. Attorney Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91 (1990); *Ibanez*, 512 U.S. 136. This makes a prophylactic ban improper for this reason as well. In a case involving a prophylactic ban on attorney advertising of certifications and licenses, the Supreme Court was unpersuaded by the state's argument that the certifications imply that an attorney with the certification is more qualified than an attorney without. *Peel*, 496 U.S. at 101-02. The Court concluded that the public could, with some effort required on their part, verify the certification and verify what it took to obtain the certification, which would then allow the public to determine for themselves if the certification really did suggest something about quality. *Id.* at 101 ("A lawyer's certification ... is a verifiable fact, as are the predicate requirements for that certification."); *see also Ibanez*, 512 U.S. at 145 (noting that there would be some effort on the part of the public because the advertisements in *Peel* did not provide contact information for the certifying entities). The Court in *Peel* explained that, among other things, it was the fact that the

speech at issue involved objective facts which were verifiable, that the speech could not properly be characterized as inherently misleading. *Peel*, 496 U.S. at 101; *see also Ibanez*, 512 U.S. at 145 n.9.

As in *Peel* and *Ibanez*, speech stating “No rbST” is an objective fact that can be verified based upon farmer and processor production certifications. As the Director admitted, if a producer does not inject his cows with rbST, then the milk that comes from those cows will not contain rbST. (Boggs Dep. 84:8-85:4.) Furthermore, it would be no more burdensome in this case than in *Peel* and *Ibanez* for consumers of dairy products to verify the claims by contacting ODA or their milk processor. And, just as in *Peel* and *Ibanez*, if consumers are curious, they could gain an understanding, perhaps more readily, of the import of the statement by calling ODA or FDA (FDA’s general information number is listed in the government pages of the phone book) (*see* S.J.R. App. III 0690) or by running a simple internet search. Indeed, a simple search run using the Yahoo search engine using the words “rbST” and “safety” resulted in links to web documents by Monsanto asserting the substance of the FDA disclaimer. *See* S.J.R. App. III 0693-0699. The search also results in a link to the Center for Food Safety, which discusses among other things, some of the objections to the use of rbST including the animal health implications. S.J.R. App. III 0700. Thus, under the reasoning of *Peel* and *Ibanez*, the fact that consumers have the ability to verify statements such as “No rbST” and readily understand the import of such statements, is an additional reason why a prophylactic ban is not proper.<sup>8</sup> Indeed, if the Department’s real concern, which is not articulated in its defense of the prophylactic ban, but which is articulated in the Governor’s February 7, 2008 Executive Order, is that dairy farmers are concerned that rbST labeling *implies* that milk that comes from cows not treated with

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<sup>8</sup> This is also a reason that militates against ODA’s insistence on specific wording for production claims and such stringent color, font, style and size requirements relating to the disclaimer.



rbST is superior, it is noteworthy that consumers already have access to the information they need to dispel that concern.

**c. Nor is the banned speech actually misleading**

Moreover, even if misleading speech standing alone could somehow justify a prophylactic ban, as ODA appears to argue (Mem. Opp'n 12-13), there remains no credible evidence of actual confusion.<sup>9</sup> As explained more fully in IDFA's opening brief, speech restrictions cannot be justified on the basis of speculation or hypothesis. *Ibanez*, 512 U.S. at 145 n.9 (explaining the only witnesses were regulators and none offered evidence that any member of the public has been misled.) (Mem. Supp. 23-25.)

Even ODA's after-the-fact testimony suggesting that the now banned speech is misleading does not establish that the harm was real. According to Director Boggs and Chief Jones, in statements made after their Opposition was filed, the purported impetus for issuing the emergency regulation was consumer communications that took place after Pennsylvania issued rbST labeling guidance that revealed confusion by consumers according to ODA. (Jones Dep. 26:3-15; Boggs Dep. 24:19-25:5.) According to Chief Jones these communications included a "barrage" of e-mails that started after October 22, 2007, when Pennsylvania issued rbST labeling guidance. (Jones Dep. 8:23-9:1.)

In fact there is no "barrage" of consumer complaints in the documents produced by ODA in response to specific requests for consumer complaints or communications regarding dairy product labeling. If there is any "barrage" of e-mails leading up to the emergency rule, it is the constant drumbeat of e-mails from Mark Armfelt on behalf of Monsanto. SSUF ¶ 25; (Jones

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<sup>9</sup> Under examination, Director Boggs asserted that he walked up to consumers in the store to ask what they thought of the labels. (Boggs Dep. 90:2-10; 90:23-91:1.) This evidence does not justify a different conclusion. This evidence is not in the rulemaking record, and the Director was unable to detail his discussions or the names of the people with whom he spoke. This is not the kind of evidence that can properly justify a ban on speech.

Dep.11:24-12:3; 12:13-20.) Nothing in writing confirms ODA's after-the-fact position that consumers sent e-mails in advance of the emergency rule that showed that they are confused.<sup>10</sup>

Indeed consumers who did comment (after the emergency rule was issued, as it turns out, not as part of a non-existent barrage before the emergency rule) reflect no confusion whatsoever. Many express the desire to have the choice to buy milk based upon how it is produced. *See, e.g.*, S.J.R. App. III 0702-0730. Some consumers indicate that while they have been told there is no significant difference between milk from cows treated with rbST and those that are not, they do not accept that statement (S.J.R. App. III 0731-0734) or do not care about the purported non-significant difference. S.J.R. App. III 0735-0736. This is not confusion. Consumers have the right to form their own views and beliefs. It is not the label that confuses them since they already know what they are asking for; nor may ODA argue that the fact that many consumers do not buy the "no significant difference" argument means that it is the labels that are confusing or misleading. In fact these communications are evidence of a well educated, intelligent consumer base who do not want or need re-education by ODA.<sup>11</sup>

In summary, therefore, there is no dispute of fact on the critical questions of whether the banned language is actually or inherently misleading. Nor is there a dispute of fact on the critical question of whether the banned language has a history of deception. Accordingly, under the Supreme Court precedent that limits prophylactic bans to very limited circumstances, ODA has

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<sup>10</sup> The existence of at most a handful (IDFA found one ) of e-mails from consumers decrying BGH or hormones as opposed to rbST or artificial hormones cannot support a finding of a barrage of consumer confusion. One letter or a handful of letters out of several thousand that is not addressed to a specific label certainly does not establish actual harm and it certainly does not support a finding that the phrases such as "No rbST" can not be placed in a context that are not confusing. In his deposition, Chief Jones asserted that if these documents existed, he would have produced them in the context of this litigation. (Jones Dep. 9:14-19; 10:8-12; 31:23-32:17.)

<sup>11</sup> ODA did not make statements until after this litigation commenced, IDFA filed its opening brief, and depositions were taken. The rulemaking record undercuts the reliability of these statements. This Court should properly disregard the statements as post-hoc rationalizations that lack reliability. *Bowen v. Georgetown Univ. Hosp.*, 488 US 204, 212 (1988); *Burlington Truck Lines, Inc. v. U.S.*, 371 U.S. 156, 168 (1962) ("The courts may not accept appellate counsel's post hoc rationalizations for agency action .....")

failed to carry its burden of justifying a prophylactic ban on the use of phrases such as “No rbST.” As such, this Court should grant summary judgment in favor of IDFA and deny ODA’s motion seeking summary judgment affirming the prophylactic ban.

**B. ODA erroneously asserts that all of the *Central Hudson* factors need not be satisfied in order to justify the Department’s multiple requirements**

**1. ODA’s Position that *Central Hudson* is inapplicable to the numerous disclaimer requirements regarding placement, font, style, case, color and size in the Rule contradicts Supreme Court precedent**

As to the Ohio Rule’s requirement of a contiguous disclaimer including acceptable wording, placement, font, style, case, size and color, ODA argues that IDFA relies on the wrong standard – that the Ohio Rule must only satisfy a lower reasonableness standard under *Zauderer*, 471 U.S. 626, because it does not ban speech, but merely requires the inclusion of a disclaimer. (Mem. Opp’n 7-8.) ODA argues that the regulation’s requirements satisfy this standard because: 1) the mandated disclaimer is true; 2) it does not require the milk processor to state its agreement with FDA’s findings; and 3) the formatting requirements are not difficult to comply with. (Mem. Opp’n 10-12.) Based solely on those three grounds and without empirical evidence to support the claim that consumers are misled, ODA asserts that the Ohio Rule’s disclaimer requirements are “reasonably related to the Ohio’s bona fide interest in preventing consumers from being misled regarding the products they consume” and thus, satisfy the *Zauderer* standard. (Mem. Opp’n 12.)

ODA does not rebut IDFA’s contention that there is no concrete evidence that the harm of misleading consumers is real, beyond its own speculative belief that the existing labeling practices are in fact misleading to consumers. ODA’s argument is premised on the assumption that the existing labeling practices are misleading, but ODA makes no effort to reference any concrete evidence from the hearing record to support that assumption. At most, ODA states that

the inability to verify the presence or absence of rbST in milk “creates an unacceptable risk of misleading consumers regarding the content of the dairy products they consume.” (Mem. Opp’n 6.) ODA does not explain how the state’s ability to verify the statement bears any relation to whether consumers understand it.

The fact that ODA cites no concrete record evidence that consumers have been misled by existing labeling practices reinforces IDFA’s position that there is none. Faced with this situation, ODA argues that the relevant standard is whether the regulation is “reasonably related” to preventing consumers from being misled and does not require it to come forward with evidence that harm is real. If accepted, ODA’s argument would require this court to hold that the state has no burden to demonstrate based on more than speculation or hypothesis that the commercial speech at issue is inherently misleading or at a minimum potentially misleading. That position, however, is not supported by the Supreme Court’s analysis in *Zauderer* and subsequent decisions that address mandated disclaimers designed to remedy potentially misleading commercial speech. To pass muster under the First Amendment, the state still has the burden to demonstrate based on more than speculation or hypothesis that the commercial speech at issue is at a minimum potentially misleading such that restricting speech by requiring an added disclaimer in a particular format is necessary to prevent any potential for deception of consumers. *Ibanez*, 512 U.S. at 146; *Mason v. Fla. Bar*, 208 F.3d 952, 958 (11th Cir. 2000). In this case, the Director has fallen well short of that burden.

ODA’s extensive quotation of the purported standard set forth in *Zauderer* is incomplete. The Supreme Court’s analysis of the disclaimer requirement imposed by the state in *Zauderer* included an evaluation of whether the speech at issue is inherently or potentially misleading. Based on the specific facts in *Zauderer* involving attorney advertising and the public’s

understanding of the difference between “fees” and “costs,” the Court determined that the state’s assumption that the speech at issue was potentially misleading was “hardly a speculative one,” even going so far as to say that the possibility for deception was “self-evident.” *Zauderer*, 471 U.S. at 652-53. The Supreme Court has a long history of evaluating cases dealing with attorney advertising which presumably made the Justices more comfortable in reaching the conclusion that it is self-evident that the speech is misleading. *See, e.g., Bates v. State Bar of Ariz.*, 433 U.S. 350 (1977); *In re R.M.J.*, 455 U.S. 191. While the state was able to easily meet its burden in the circumstance presented in *Zauderer*, the Court at no point in *Zauderer* or in subsequent cases held that in the context of mandated disclaimers, the state no longer has the burden of demonstrating that the speech at issue is inherently or potentially misleading.

The Supreme Court’s decision in *Ibanez*, 512 U.S. at 146, decided after *Zauderer*, reinforces the fact that even in the context of mandated disclaimers, the state is not relieved of the burden of coming forward with concrete evidence that the speech at issue is inherently or potentially misleading and that the measure will alleviate the harm to a material degree. This is a critical factor under the *Central Hudson* test. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (quoting *Edenfield*, 507 U.S. at 771). The *Ibanez* decision also demonstrates that the ease with which the state was able to satisfy that burden in *Zauderer* was more the result of the specific facts presented in that case than the Supreme Court’s intent to relax the standard for evaluating state mandated disclaimers intended to reduce the likelihood of misleading consumers and the state’s burden to justify such measures.

*Ibanez* involved a challenge to a decision by the Florida Board of Accountancy reprimanding an attorney for including her “CFP” (Certified Financial Planner) designation in advertising for her law practice. *Ibanez*, 512 U.S. at 138. One argument presented by the Board

was that the reprimand was appropriate because the advertising was “potentially misleading” entitling the Board to enact measures short of a total ban to prevent deception or confusion (i.e., require a disclaimer). *Id.* at 146. The Supreme Court rejected the Board’s disclaimer argument (even citing to *Zauderer*) stating:

If the “protections afforded commercial speech are to retain their force,” *Zauderer*, 471 U.S., at 648-649, we cannot allow rote invocation of the words “potentially misleading” to supplant the Board’s burden to “demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.” *Edenfield*, 507 U.S. at 771.

...Given the state of this record – the failure of the Board to point to any harm that is potentially real, not purely hypothetical – we are satisfied that the Board’s action is unjustified. We express no opinion whether, in other situations or on a different record, the Board’s insistence on a disclaimer might serve as an appropriately tailored check against deception or confusion, rather than one imposing “unduly burdensome disclosure requirements [that] offend the First Amendment.” *Zauderer*, 471 U.S. at 651.

*Ibanez*, 512 U.S. at 146 (emphasis added).

The *Ibanez* decision is on all fours with the present case. Like the Board in *Ibanez*, ODA has not come forward with any concrete evidence to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree. Throughout its Opposition, ODA simply relies on nothing more than the bald assertion that the existing labeling practices are misleading, but without any supporting evidence, this amounts to nothing more than speculation. *Ibanez* unequivocally holds that such “rote invocation” of the word “misleading” – as ODA does in this case – is insufficient to meet the state’s burden of requiring a disclaimer on commercial speech. *Id.* And, ODA’s unsupported assertions are belied by the multiple findings of the FDA and the FTC that with very limited exceptions, the existing dairy labeling practices related to rbGH are not misleading. (Mem. Supp. 4-5.) Thus, the present case is clearly not a circumstance like *Zauderer* where one can conclude that it is “self-evident” that the speech at issue is potentially misleading thereby relieving ODA of its burden to come forward with

concrete evidence to support the conclusion that the existing labeling practices are either inherently or potentially misleading.

ODA also erroneously relies on the Second Circuit's decision in *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001) for the position that *Zauderer* and the "reasonable relationship" test is the only applicable standard for evaluating state mandated disclosures under the First Amendment. (Mem. Opp'n 9.) *Sorrell's* characterization of *Zauderer* is contradicted by *Ibanez* which applies the *Central Hudson* test, especially as to the state's obligation to come forward with evidence to demonstrate that there is a real harm even for measures that do not involve a total ban. *Ibanez*, 512 U.S. at 146.<sup>12</sup> Indeed *Sorrell* never even mentions *Ibanez*, a case decided nine years after *Zauderer*. Perhaps the *Sorrell* court was unaware of *Ibanez* as neither side in briefing *Sorrell* cites the case. S.J.R. App. III 0737-0778.

The U.S. Supreme Court cases to the extent they permit more regulation of speech, first apply *Central Hudson* as to the first three prongs of the test. Only then is there any suggestion, by non-majorities, that less strict scrutiny is permitted for the purpose of deciding whether the regulation meets the reasonable fit test – only one prong of *Central Hudson*. The first three prongs of *Central Hudson* do not get that benefit.<sup>13</sup> The bottom line is that this Court need not reach the issue that perplexes ODA because like Florida in *Ibanez*, Ohio has not met its predicate burden under *Central Hudson* of proving that the production claim is actually misleading.

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<sup>12</sup> Even if *Sorrell* is right in that the fourth prong of *Central Hudson* is relaxed to some undefined level called "unduly burdensome" (or ODA's relaxed fit test), the Rule is unduly burdensome as explained below.

<sup>13</sup> Nor is *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) cited in *Sorrell* helpful to ODA. The statements in Parts III (general comments regarding standard of review) and IV (less rigorous review accorded to added disclaimers) are clearly *dicta* because speech was banned – it was not a disclaimer or compelled speech case. More importantly those parts of Justice Stevens' Opinion are not joined by the majority and they are flatly contradicted by *Ibanez*. The only dispute in the U.S. Supreme Court as to the standard of review in commercial free speech cases is limited to the question of whether some commercial speech ought to be afforded the same protections as non-commercial speech (thus *Central Hudson* provides review that is not rigorous enough). See, e.g. *Greater New Orleans Broad. Ass'n v. U.S.*, 527 U.S. 173, 184 (Majority Opinion) & 197 (J. Thomas concurring in the Judgment) (1999).

Moreover, ODA is wrong to claim that the Rule here is designed as compelled speech ala *Sorrell*.<sup>14</sup> Just as with *Ibanez*, if milk processors chose not to make the “no use of rbST” claim, there would be and indeed is no requirement to speak. As in *Ibanez*, once a milk processor chooses to speak on this subject, the processor then is restricted in that speech by being told to make additional statements in the form and manner proscribed by the Rule. In *Sorrell*, the manufacturers did not wish to speak at all about the presence of mercury in their products. If *Sorrell* can be reconciled with *Ibanez*, it must be that the Second Circuit viewed compelled speech regarding a required health warning differently from how the Supreme Court views restricted speech where additional words are required of someone who chooses to speak to reduce the potential for misleading consumers.<sup>15</sup>

Since Ohio claims that there is no difference between milk from cows treated with rbST and cows not treated with rbST, it would be silly for ODA to claim that it is “affirmatively protecting” Ohio consumers health; Chief Jones admitted that any potentially misleading labels prior to the Rule were not pursued because “it wasn’t a food safety issue.” (Jones Dep. 41:23-42:4.) ODA instead says it is trying to prevent consumers from being misled into thinking that there is a health issue. This is vastly different from Vermont trying to protect both its environment and citizens from the health hazards of mercury.<sup>16</sup> If *Sorrell* provides any guidance

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<sup>14</sup> *Sorrell*’s reliance on *Zauderer* for the proposition that adding information is different in some way from preventing information is contradicted by the fact that in *Ibanez* the Court applied the same tests from *Edenfield* and *Zauderer* (applying *Central Hudson*) for both the ban portion of the speech and Florida’s effort to provide “somewhat more information than they might otherwise be inclined to present.” *Zauderer*, 471 U.S. at 650.

<sup>15</sup> The Ohio Rule deals with consumer information like *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67 (2nd Cir. 1996) and *Ibanez*. *Sorrell* is a case regarding critical environmental safety and human health based upon the presence of mercury in certain light bulbs. The panel in *Sorrell* struggled with that Circuit’s case in *Amestoy*. *Sorrell* distinguished *Amestoy* on the ground that Vermont’s interest went beyond merely satisfying “consumer curiosity” to affirmatively “protecting human health and the environment from mercury poisoning.” *Sorrell*, 272 F.3d at 115 n.6 & 115. Although the court recognized that the state’s environmental goals were “inextricably intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products,” the statute passed constitutional muster in part because Vermont did not defend it based solely on consumer awareness for its own sake. *Id.* at 115.

<sup>16</sup> Curiously in its Brief citing *Sorrell*, the Director neglects to complete the court’s quotation referencing mercury.



at all, it serves as a reminder that it is not a substantial government interest to justify mandating language merely to satisfy consumer curiosity as ODA seems to have done here with the Director's attempts at providing "balanced" information to consumers.

Moreover, *Sorrell*'s focus on whether there is a reasonable relationship between the means and ends of a disclosure requirement concerning human health and environmental safety cannot reasonably be interpreted as broadly as ODA suggests -- that the *Central Hudson* test is inapplicable to all measures that do not involve a total ban. When *Sorrell* is viewed in its entirety, the court evaluated the same issues as would be required under *Central Hudson*. The "reasonable relationship" test used in *Sorrell* is the final prong of the *Central Hudson* test where the court must determine whether there exists a reasonable fit between the government's goals and the means chosen to accomplish it. See *Lorillard Tobacco v. Reilly*, 533 U.S. 525, 556 (2001). The court also satisfied itself that the disclosure requirement satisfied a legitimate and substantial government interest -- another factor required under *Central Hudson*. *Sorrell*, 272 F.3d at 115.

While ODA says that the multi-prong test in *Central Hudson* does not apply at all to disclosure requirements, other circuits have been clear in finding, as in *Ibanez*, that the *Central Hudson* test applies to disclosure requirements. In *Mason*, 208 F.3d 952, the *Central Hudson* factors are applied to a requirement that an attorney provide a disclaimer in his advertisement explaining the meaning of the AV rating in Martindale-Hubbell. See also *Borgner v. Brooks*, 284 F.3d 1204, 1206-07 (11th Cir.), *cert denied*, 537 U.S. 1080 (2002) (applying all of the *Central Hudson* factors to a state requirement that dentists include disclaimers to prevent potential consumer confusion). The Seventh Circuit also did not apply the relaxed "reasonable relationship" test to government imposed disclosures stating that such requirements must be no

broad than necessary to prevent the deceptive or misleading advertising. *Commodity Trend Serv., Inc. v. Commodity Futures Trading Comm'n*, 233 F.3d 981, 994 (7th Cir. 2000) (discussing applicable standard for imposing affirmative disclosures but deciding issue is not ripe for decision because crucial facts were not in record).

The facts in *Mason* are more analogous to the present case than those in *Sorrell* where the purpose of the mandated disclosure was solely to protect human health and the environment from mercury poisoning. In *Mason*, the state bar asserted that it had an interest in ensuring that the public has access to relevant information to assist in the comparison and selection of attorneys. *Mason*, 208 F.3d at 956. This position is akin to ODA's statement here that the disclaimer is necessary to provide consumer with relevant information to ensure that when purchasing milk, the consumer is not misled into thinking that milk from non-rbGH treated cows is superior to other milk. (See Mem. Opp'n 16.) Much like ODA here, the state bar failed to produce any concrete evidence of identifiable harm other than unsupported speculation in support of the disclaimer requirement. *Mason*, 208 F.3d at 958. Relying on *Ibanez*, the *Mason* court rejected the argument of the state bar that the restriction should be upheld because it merely required the use of a disclaimer stating:

Even partial restrictions on commercial speech must be supported by a showing of some identifiable harm. Accordingly, we hold that the Bar is not relieved of its burden to identify a genuine threat of danger simply because it requires a disclaimer, rather than a complete ban on Mason's speech.

*Id.* (emphasis added).

In sum, the Supreme Court's decision in *Ibanez* provides this Court with a clear direction that even in the context of disclaimer requirements intended to reduce the likelihood of misleading consumers, ODA still has the burden to demonstrate that the harms it recites are real and that the disclaimer requirement will in fact alleviate them to a material degree. See *Ibanez*,

512 U.S. at 146 (quoting *Edenfield*, 507 U.S. at 771). ODA has made no attempt to meet this burden, relying instead on an untenable legal argument that in effect seeks to do an end run around his burden.<sup>17</sup>

**2. Even if ODA correctly stated the standard of review, the Ohio Rule is nevertheless unduly burdensome**

Even the relaxed standard articulated by ODA fails to justify the Ohio Rule's requirement of a contiguous disclaimer conforming to the regulation's strict requirements as to acceptable wording, placement, font, style, case, size and color. Under *Zauderer*, a mandated disclosure requirement can still run afoul of the First Amendment if it is "unduly burdensome." *Zauderer*, 471 U.S. at 651. The *Zauderer* decision, however, does not provide any detailed discussion of the standards for an "unduly burdensome" disclosure requirement because the record in that case did not contain details about the precise disclosures that were required.<sup>18</sup> *Id.* at 653 n.15 (noting the difficulty to evaluate whether the disclosures were unduly burdensome without specific information in the record about precisely what disclosures were required). Nevertheless, the numerous requirements on the disclaimer imposed by the Ohio Rule are empirically "unduly burdensome."

The requirement that the disclaimer be placed contiguous to the claim and in exactly the same font, style, case, and color and at least half the size as the claim obscures the basic message of the claim and restricts the processors' freedom to design a concise and easily recognized label that truthfully informs consumers of the basic message that the milk is from cows not treated

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<sup>17</sup> Chief Jones admitted that some of the now-banned language is not misleading in itself and the disclaimer portion of the Rule is about giving information to the consumer. (Jones Dep. 51:23-52:6.)

<sup>18</sup> Justice Thomas, joined by Justice Ginsburg, in a dissent to the Supreme Court's denial of certiorari in *Borgner*, expressed doubt, that given the particular circumstances in *Zauderer*, that *Zauderer* could even serve as helpful authority to justify a mandated disclaimer where the state specifies the disclaimer's wording, placement, font, style, case, size and color. *Borgner v. Fla. Bd. of Dentistry*, 537 U.S. 1080 (2002). Demonstrating that the Supreme Court remains of the view that the multiple prongs of the Central Hudson test apply to an analysis of disclaimer requirements, the dissent noted that the extent of the disclosure requirements could affect whether the state is able to satisfy the fourth prong of *Central Hudson*. *Id.*

with rbGH. *See id.* at 647 (discussing importance of illustration in conveying a message in advertising). For example, the requirement that the claim and the disclaimer be in the same font and color eliminates two means of differentiating the basic message of the claim from the contextual disclaimer. These simple devices of using different fonts or font colors for the claim and the disclaimer can have a significant visual impact that improve the readability of the label and have regularly been used by processors relying on the FDA guidance. The Ohio Rule, however, would prohibit processors from using such methods because ODA concluded for unexplained reasons that the label is misleading unless the claim and the disclaimer are in the same font and color. The Ohio Rule imposes a further undue burden and acts to chill commercial speech because the same rigid requirements apply uniformly regardless of the size of the container, which has the practical effect of precluding commercial speech about rbGH on smaller containers. SSUF ¶ 55.

IDFA has also presented evidence that the Ohio Rule will impose substantial direct costs on dairy processors to change their labels to comply with the new requirements. ODA's cost estimate of \$250-400 per label to comply with the Ohio Rule (Mem. Opp'n 4) grossly understates the actual cost to the dairy processors.<sup>19</sup> ODA's figures clearly do not account for all of the costs associated with compliance as demonstrated by the numerous declarations submitted by IDFA and OTA in their motions for preliminary injunction. SSUF ¶¶ 60, 67. In fact, when ODA contacted the processors to obtain cost estimates, Chief Jones only asked a general question that did not delve into what costs are reflected in those estimates. (Jones Dep. 63:7-64:6.)

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<sup>19</sup> It is curious how ODA could be in a position to conclude the label changes under the Rule would not be unduly burdensome when they did not have estimates showing the full extent of the costs included in changing labels. (Jones Dep. 63:7-64:6.)

ODA points to the fact that several processors have received approval for their labels suggesting that the burden of the Ohio Rule is minimal. (Mem. Opp'n 4, 25.) The mere fact that the processor has received approval provides no insight into the total costs incurred by the processor to get that approval and to ensure that all of the brands it sells in Ohio comply with the Ohio Rule, which is in the tens or hundreds of thousands of dollars, and for some, in excess of \$240,000. SSUF ¶ 60. On top of these direct costs of making changes to the label, there are significant new and ongoing costs for distribution, labor and/or warehouse space. SSUF ¶ 67. Additionally, ODA only considered costs associated with changing the Ohio label. (Jones Dep. 71:14-72:15.) Thus, ODA's estimate did not account for the fact that the Ohio Rule necessitates processors with national brands to incur costs to change and obtain approval of the labels in other states to assure national uniformity of the packaging for sale in interstate commerce. SSUF ¶¶ 63-67. ODA is imposing all of these costs on the processors to modify their existing labels that the FDA and FTC have repeatedly determined are not misleading.

In conclusion, the *Central Hudson* test still applies to Ohio Rule's disclaimer requirement regardless of the fact that it does not ban speech. And, the Director has not satisfied his burden to justify imposing the requirement of a contiguous disclaimer conforming to the regulation's requirements as to acceptable wording, placement, font, style, case, size and color. The strict disclaimer requirements are also unduly burdensome, so they would still fail to satisfy even the lower reasonableness standard from *Zauderer* advocated by the Director. As such, this Court should find that the Ohio Rule is an unconstitutional infringement on truthful, non-misleading commercial speech.

**II. ODA's superficial Commerce Clause analysis ignores relevant case law and important undisputed facts**

**A. The Rule directly burdens interstate commerce**

ODA erroneously argues that the Rule does not directly burden interstate commerce: “[n]othing on the Rule’s face mandates or regulates any label on products offered for sale in other states.” (Mem. Opp’n 21.) This assertion misses the point of the direct burden jurisprudence.

Under the price affirmation cases, a regulation that regulates local activity can have the *practical effect* of regulating conduct beyond the regulating state’s border. *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989). It is this *practical effect* that can render an otherwise local regulation violative of the negative Commerce Clause.<sup>20</sup> In *Healy*, the price affirmation statute addressed only pricing within Connecticut just as the Rule at issue here is on its face aimed at labels used in Ohio. *Healy*, 491 U.S. at 337. Regardless, the price affirmation statute nevertheless was found to directly burden interstate commerce because if wholesalers wanted to sell product in Connecticut without violating the price affirmation statute, they had to, *as a practical matter*, alter their conduct in the neighboring states. *Healy*, 491 U.S. at 337-38; *see also Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 583 (1986) (“That the ABC Law is addressed only to sales of liquor in New York is irrelevant if the ‘practical effect’ of the law is to control liquor prices in other States.”).

The practical realities of the dairy industry as explained in the opening brief and declarations submitted therewith, dictate that as a result of the Rule, milk processors have the same problem that beer wholesalers faced in *Healy*. Mem. Supp. 30; SSUF ¶¶ 52-53, 62-66. In

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<sup>20</sup> *Eisenberg* is unhelpful to ODA because the local transaction involved so little interstate commerce relative to the field being regulated. *Milk Control Bd. v. Eisenberg Farm Prods.*, 306 US 346, 353 (1939). Here a substantial portion of the field being regulated is from out-of-state.

order to be able to sell their national brands in Ohio, they must choose between abandoning rbST labeling or changing their national labels to meet the requirements of Ohio's Rule. This is because the national processors serve national retailers that have complex distribution systems. These distribution systems are not designed to handle multiple labels for the same product based on state of destination. P.I. App. 0422, ¶ I; 0454-0455, ¶6, 0452, ¶ 11. These processors will be forced to change their national labels to meet the Ohio Rule if they wish to retain their Ohio market.

Importantly, Ohio was not unaware of these extraterritorial impacts. On March 13, 2008, the Director indicated that anyone with sales out of Ohio would not need to worry about different label regulations among the states so long as they complied with Ohio's strictest rule. SSUF ¶ 57. The Director reiterated this point on September 3, 2008 in response to a question of whether he had talked to a national processor to ask how they would go about complying with Ohio's Rule, stating:

[Kraft] said it is very expensive to have a set of labels only for Ohio and a different set for the rest of the country. We pointed out to them that the labeling in Ohio, if they could be used throughout the country, they didn't have to change it. But if they chose to, that was their choice.

(Boggs Dep. 65:20 – 66:2; *see also* Boggs Dep. 74:4-8.)

At that time, however, the Director acknowledged a flaw in the Rule; Ohio cannot be sure that their Rule will be the strictest for long. According to the Director, Utah may ban rbST labeling altogether. (Boggs Dep. 101:3-5.) As more states enter the fray in order to protect the interests of their rbST-using dairy farmer constituents, the greater the risk that processors will find themselves paralyzed in their ability to provide milk to consumers who want to know if rbST was used in the production of their milk. According to the Supreme Court, this is unacceptable under the Commerce Clause. *Healy*, 491 U.S. at 334.

By going beyond the FDA guidance that has worked for nearly 14 years and in light of the practical realities of today's dairy distribution systems, the Rule will: (1) cause the citizens of other states, whose governments actually encourage rbST labeling such as Maine, Vermont and Wisconsin, to be subjected to Ohio's stricter albeit less consumer friendly rule because of the features of the Rule that obscure the "No rbST" message; and (2) create the very real possibility that processors will not be able to, using one national label as required by the practical realities of serving national retailers, comply with the rules of different states. These are precisely the consequences that the Supreme Court's jurisprudence seeks to prevent.

**B. The Rule discriminates against out-of-state processors and dairy farmers that have established a niche in rbST advertising**

ODA's claim that the Rule is not discriminatory is based on a misunderstanding that pervades its entire Commerce Clause defense. The test for discrimination is not necessarily equal treatment, but rather a measure of disparate impacts. The Supreme Court long ago recognized that states will be clever and not forthright in their efforts to protect local industry. *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 201 (1994) ("The commerce clause forbids discrimination, whether forthright or ingenious. In each case it is our duty to determine whether the statute under attack, whatever its name may be, will in its practical operation work discrimination against interstate commerce." (quoting *Best & Co. v. Maxwell*, 311 U.S. 454, 455-56 (1940))). As such, it has recognized that even-handed regulations have unlawful impacts that can rise to the level of a per se violation of the negative Commerce Clause. For instance, the Court acknowledged in *Washington Apple* that the statute was facially neutral but still went on to analyze the *practical effect* of the statute on the Washington apple growers, just as this Court must here. *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333, 350 & 352 (1977).



ODA then struggles to distance its own Rule from the statute in *Washington Apple* on the basis of three facts. (Mem. Opp'n 23-24.) Importantly, ODA only discusses two out of three reasons cited by the Court as a basis for finding discrimination. Presumably ODA failed to address the third reason cited, which was that the statute would have a leveling effect (*Washington Apple*, 432 U.S. at 351), because ODA knew it lacked the facts to distinguish the Rule here from the statute at issue in *Washington Apple*. To the contrary, as between those processors that have established labels that are based on market research, and those that may enter the business of rbST labeling anew, the Rule denies processors the opportunity to differentiate their messages. This forces those who were market leaders to give up their earned advantages.

ODA argues that the Rule does not raise the cost of doing business in Ohio for out-of-state entities while leaving in-state entities alone, arguing instead that the Rule applies equally to both in- and out-of-state entities. (Mem. Opp'n 23.) ODA ignores the fact that was recognized in *Washington Apple*; that because out-of-state processors, in particular those doing business nationally, have an established practice that must be changed, the out-of-state entities will bear the burden of the costs. Like the choices that Washington apple growers had before them, national processors such as Kraft, Tillamook, Shamrock and Ben & Jerry's that already had rbST labeling in use will have to choose between maintaining a special label for Ohio (the Washington growers listed this option) and stop using their system of using the same labels nationally without the need for segregation in distribution warehouses (the Washington growers listed this option), or abandon rbST labeling altogether (the Washington growers listed this option). *Washington Apple*, 432 U.S. at 338. And, just as in *Washington Apple*, Ohio dairy farmers and their processors not previously engaged in rbST labeling would not be forced to alter their

marketing practice at all – they would only have to comply with Ohio’s Rule if they chose to enter into rbST labeling. There would not be a cost associated with changes such as obliteration of existing labels. All indications are that the Rule was intended to prevent rbST labeling from becoming entrenched in Ohio such that Ohio dairy farmers would be unaffected by the nationwide rbST labeling movement.

Second, ODA says that the North Carolina requirements effectively imposed a downgrade on Washington apple growers and then erroneously asserts that no such downgrade is caused by the Rule at issue here. (Mem. Opp’n 24.) The undisputed facts establish that there is a downgrade. IDFA members have developed their labels to address what their market research has shown consumers want. SSUF ¶ 8. For instance, the Rule interferes with Shamrock’s ability to communicate to the consumer in an accurate and truthful manner, which market research has shown is important to Shamrock’s customers. As such, the Ohio Rule directly threatens Shamrock’s sales results and their ongoing ability to compete on the entirety of attributes of their products which is their unique position.. P.I. App. 0422, ¶ H.1. Similarly, the Rule is a downgrade for Hood as well. They have been developing their rbST labels over a period of years in order to respond to consumer requests for information regarding the use or non-use of rbST. P.I. App. 0428, ¶¶ 8-10. The Rule, with requirements such as specific wording, banned wording, placement, font size, style and color restrictions, will no doubt wash out the many attributes that these companies have worked so hard to develop over the years. *See also* P.I. App. 0452, ¶¶ 6 -8. Moreover, ODA’s Rule certainly does not reflect that which consumers

want or what the processors with existing labels have determined is needed to meet the needs of consumers and have a successful brand.<sup>21</sup>

Further, it is without question a downgrade to the extent the Rule tarnishes the reputation of those processors that have been using labels that ODA has now asserted by government fiat are false and misleading. P.I. App. 0422, ¶ H2; 0433-44, ¶¶ 5.1-5.4. This is a terrible result for processors that work to gain the public's trust and their purchasing power on a daily basis. This is without question a downgrade.

Third, ODA asserts that *Washington Apple* does not apply because the statute was aimed at closed containers, which essentially meant the statute was aimed at those doing business in interstate commerce. (Mem. Opp'n 24.) This point was raised by the *Washington Apple* court as an indication that the North Carolina statute was protectionist by design. *Washington Apple*, 432 U.S. at 352 ("Moreover, we find it somewhat suspect that North Carolina singled out only closed containers of apples, the very means by which apples are transported in commerce, to effectuate the statute's ostensible consumer protection purpose when apples are not generally sold at retail in their shipping containers."). It was not listed as a basis for the Court's conclusion that there was discrimination.

Nevertheless, a similar circumstance does in fact exist here. The fact that Ohio processors were only just beginning the process of using rbST labeling in response to competition from national processors and their dairy farmers, is tantamount to ODA targeting interstate commerce as was the case in *Washington Apple*. Ohio dairy farmers wanted ODA to

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<sup>21</sup> No formal surveys or studies were undertaken with respect to what consumers want or need. (Jones Dep. 36:18-24.) Director Boggs indicated that the decisions about what could be on the labels were made by Director Boggs and his staff. (Boggs Dep. 75:23 – 76:2.)

stop the rbST labeling movement before it started so that they would not have to stop using rbST. SSUF ¶ 32.

The undisputed facts reveal that there was an established market for dairy products produced outside of Ohio that have been marketed in Ohio as being produced from cows not treated with rbST. SSUF ¶¶ 49 & 52. This put pressure on Ohio processors to meet the competition and thus they announced that effective February 1, 2008, milk would have to be from cows not treated with rbST. SSUF ¶ 21. Dairy farmers wishing to stem the movement away from the use of rbST turned to the Department for help. SSUF ¶¶ 27 & 32. The rulemaking record reveals that dairy farmers, not consumers, asked the Department to ban or severely restrict rbST labeling.<sup>22</sup> SSUF ¶¶ 26 & 29-35. Director Boggs admitted that dairy farmers asked for the Department's help because they had "to make decisions as to whether or not [they were] going to continue to use Posilac or not." (Boggs Dep. 22:20-22.)

The Director's explanation of how the Rule would help dairy farmers defies logic and thus suggests another unstated answer to the question of how the Rule would help dairy farmers. Unless ODA was going to ban rbST labeling or, as it has done, adopt labeling that is so restrictive as to make the labeling an uneconomic marketing tool, a rule about the contours of rbST labeling would not determine whether processor acceptance of rbST would suddenly change course.

Instead, the undisputed facts reveal that the Rule has gone beyond that which is necessary to ensure accuracy (see Mem. Supp. 4-5 (discussing FDA guidance)) and has adopted labeling requirements that are so restrictive that rbST labeling will prove an unhelpful marketing tool or

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<sup>22</sup> In *Washington Apple*, the Supreme Court pointed out that although a finding of protectionist intent was not necessary because discrimination was present, an indicator that there was protectionist intent stemmed from the fact that the North Carolina apple producers were mainly behind the disputed legislation. *Washington Apple*, 432 U.S. at 352.

too costly to continue. SSUF ¶¶ 50, 55, & 60. This together with the absence of any concrete evidence that consumers were actually misled by existing labeling in the marketplace (as explained in Part I above), reveals that the Rule is really aimed at helping Ohio dairy farmers. Whichever course processors take in response to the Rule, it will no doubt provide benefits to Ohio farmers seeking to keep their processors from demanding rbST and it is therefore protectionist.

Given the circumstances that existed when the Ohio Rule was being considered and then adopted, it is clear that the Rule addressed the very issues that the North Carolina statute in *Washington Apple* did and as discussed herein as well as IDFA's opening brief, the Ohio Rule simply must be struck down as discriminatory.

**C. The benefits of the Rule do not outweigh the burdens as required under *Pike***

Ohio does not address a critical question required by the *Pike* analysis, which is whether the objective can be achieved by lesser means. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970) ("[T]he extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.") As discussed in IDFA's opening brief, the answer is a resounding yes. Chief Jones admits that the FDA guidance was in fact working fine, with no consumer complaints or enforcement actions to speak of prior to October 22, 2007. (Jones Dep. 22:16-18; 22:24 – 23:4.)

Moreover, ODA has essentially ignored the burdens on interstate commerce in asserting that the benefits of the Rule outweigh the burdens. ODA has demonstrated that they quite clearly have not considered the full spectrum of costs that will be imposed on those doing business in interstate commerce as articulated by IDFA's members. SSUF ¶¶ 31, 60 & 67; Mem.

Supp. 7, 38. Director Boggs testified that their cost estimates were only for changing labels in the state of Ohio. They were not concerned with what their regulation would cost processors that would have to change labels in other states or to have separate labels in other states. (Boggs Dep. 66:23-67:18; Jones Dep. 63:7-67:11, 71:14-72:15.) Moreover, Chief Jones testified that he did not know for sure what the cost estimates they used included. (Jones Dep. 63:7-64:6). Thus the cost estimates relied upon by the Department lack credibility and in no way serve to dispute the much more significant cost estimates set forth by IDFA members. SSUF ¶¶ 31, 60 & 67.

In addition, neither the Director nor Chief Jones manifested any understanding of how national processors do business and frankly they indicated that they were unconcerned with the costs and the logistical and regulatory hurdles these processors would face indicating that their only concern was what it would cost to change a label *for Ohio*. (Boggs Dep. 66:23 – 67:18; Jones Dep. 71:14-72:15.)<sup>23</sup> Without this knowledge about today's modern distribution systems, any conclusions by the Chief regarding the ease or difficulty national processors would have in complying with the Rule lack credibility.

Further, ODA's scant burden analysis is not helped by their assertion that the burdens cannot be so great since ODA has already approved a number of labels. The fact that ODA has approved a number of revised label applications does not reflect the cost or the level of the burden these processors will experience if they are forced to execute on these label changes. Indeed, there is no evidence these changes have actually been made (Jones Dep. 70:3 – 71:1.) At best, these label applications may reflect contingency planning by processors. But, there is no evidence these companies have obtained approvals from their customers to print the labels that

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<sup>23</sup> For instance, Chief Jones was not familiar with the term stock keeping unit. (Jones Dep. 72:20 – 73:4.) This is a basic term in the modern world of food distribution. It drives decisions by retailer customers and is one of the many reasons IDFA's members have indicated that they may not be able to maintain a separate label for Ohio and thus may be forced to abandon rbST labeling for some customers. P.I. App. 0422, ¶ I; 0434, ¶ 7; 0462, ¶ 10.

have been submitted for approval or that they have definitely concluded that it is cost-justified to go forward with the new labels.

Further, as discussed in IDFA's opening brief, ODA has not demonstrated that harm that they purportedly seek to address with the adoption of the Rule is real. As explained throughout IDFA's papers, the facts reveal that the harm asserted is pretext for helping producers protect their production methodology. It is beyond doubt that protecting Ohio producers from the demands of the national marketplace simply cannot justify the significant costs that will be borne by national processor affected by this Rule.

For these reasons, as well as the reasons set forth in IDFA's opening brief, wherein it is demonstrated that the burdens outweigh the benefits of the Rule, the Rule does not pass muster even under the less rigorous *Pike* analysis.

### **CONCLUSION**

For all of the foregoing reasons, the Ohio Rule should be found unconstitutional as a matter of law.

Respectfully submitted,

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